NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

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January 30, 2006

VIA FAX: (301) 827-6870
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Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, Maryland 20852

Re: Docket No. 2005P-0411
Comments to Citizen Petition Filed on Behalf of Wyeth

Dear Sir or Madam:

The National Community Pharmacists Association (NCPA) respectfully submits the following comments in response to the October 6, 2005 Citizen Petition filed by Wyeth to prohibit pharmacists from compounding customized prescriptions upon receipt of a physician's prescription or order for bio-identical hormone replacement therapies (BHRT). The petition suggests far-reaching restrictions on a physician's ability to prescribe and a pharmacist's ability to prepare and dispense bio-identical hormones. Not only would enactment of this petition compromise the health of thousands of women who benefit from BHRT, its broad implications would endanger all patients' access to pharmacist-compounded medications.

The NCPA supports and seeks to guarantee pharmacists' ability to compound prescriptions – one of the essential elements of the profession of pharmacy and the U.S. healthcare system. Approximately 71% of community pharmacies dispense customized medications for patients when presented with a prescription from a licensed prescriber.

On July 9, 2002, the National Heart, Lung, and Blood Institute (NHLBI) announced that it was stopping the combination conjugated equine estrogen/medroxyprogesterone acetate (Prempro) study being performed as a part of the Women's Health Initiative (WHI). This study was conducted to assess whether long term use of Prempro would reduce the risk of coronary heart disease (CHD) in postmenopausal women. It was stopped early (after an average of 5.2 years on study) because the overall health risks of Prempro, particularly for invasive breast cancer and CHD, exceeded the benefits of the drug, which included a lower rate of fractures and a reduction in the risk of colorectal cancer.[1]

Due to the results of this study, and the results of the WHI estrogen alone substudy[2] released March 2004, the treatment of symptomatic menopausal women with Hormone Replacement Therapy (HRT) changed significantly. The most recent FDA Menopause and Hormones Fact Sheet[3] (July 2005) recommends that menopausal hormone therapy should be used at the lowest doses for the shortest duration to reach treatment goals. In many cases, women are offered a standard brand, one-size-fits-all therapy when they seek relief for the physical symptoms associated with hormonal changes. In response to a physician's prescription, compounding pharmacists prepare BHRT prescriptions that have been customized for individual patients needs, therefore ensuring, as the FDA recommends, that the patient receive the lowest possible dose of menopausal hormone therapy.

2005P-0411 C515

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NCPA would like to reiterate that pharmacist compounding, an integral part of the practice of pharmacy, occurs in response to a licensed physician's prescription order for a specific compounded medication. Millions of Americans have unique health needs that off-the-shelf, prescription medicines cannot meet and they rely on the customized medicines – prescribed or ordered by their licensed physicians and mixed safely by trained, licensed pharmacists – to treat their unique conditions. It is important that the scope of the practice of pharmacy is not redefined to eliminate compounding, and that pharmacist compounding continue to be recognized as a right of the physician-patient-pharmacist relationship so that patients can continue to receive appropriate medication treatment.

Laws in all states, the FDA, the U.S. Supreme Court, Congress, and virtually every major association of healthcare professionals recognize the value of pharmacist compounding. Patients with unique needs rely more heavily on compounded medications than the general population – including home healthcare patients, hospice care patients, cancer patients, hospital patients on intravenous medicines, pain management patients, dental patients, dermatological patients, and others. Recognizing the important role the compounding pharmacist plays in this day of personalized medicine; NCPA is a founding member of the Pharmacy Compounding Accreditation Board, a voluntary accreditation body formed by eight pharmacy organizations to establish high quality standards for compounding pharmacies. These organizations and pharmacists themselves believe that standards against which they can be measured are not only good for the patient, but also good for the practice of pharmacy.

As you know, the practice of pharmacy, including the preparation of pharmacist compounded medications, is regulated by state boards of pharmacy and as government agencies, already have the rights of "seizure and injunction" that Wyeth is asking for the FDA to implement. Therefore, acceptance of this petition would not only be redundant but may preempt existing state laws.

We respectfully request that the FDA deny Wyeth's petition contained in Docket No. 2005P – 0411. NCPA believes compounding to be an essential service community pharmacists provide to physicians and patients alike. And, we support the tradition and right of the pharmacist to continue to compound without another layer of regulations. Lastly, a favorable decision on the Wyeth petition would be far-reaching and have a negative impact on physicians and patients because it would prevent pharmacists from ensuring that their patients' have access to the right prescription at the right dose for their specific illnesses.

Thank you for the opportunity to submit these comments.

Sincerely,

Bruce T. Roberts, CEO and EVP

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References:

1. FDA Statement on the Results of the Women's Health Initiative (8/13/2002). (http://www.fda.gov/cder/drug/safety/WHI_statement.htm)

2. FDA Statement on the Results of the Women's Health Initiative (Updated 04/19/2004). (http://www.fda.gov/cder/drug/infopage/estrogens_progestins/Q&A.htm)

3. FDA Menopause and Hormones Fact Sheet (July 2005) http://www.fda.gov/womens/menopause/mht-FS.html

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